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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/575,562	04/12/2006	Masato Shirai	KUZ0029US.NP	1387

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EXAMINER

ORWIG, KEVIN S

ART UNIT	PAPER NUMBER
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1611

NOTIFICATION DATE	DELIVERY MODE
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10/29/2008

ELECTRONIC

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Notice of the Office communication was sent electronically on above-indicated "Notification Date" to the following e-mail address(es):

poreilly@licataandtyrrell.com

Office Action Summary	Application No.		Applicant(s)	
	10/575,562		SHIRAI ET AL.	
	Examiner		Art Unit	
	Kevin S. Orwig		1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-7 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☒ Claim(s) 1-7 is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☐ Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|----------------------------------------------------------------------------------------|-------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>4/12/06</u> . | 6) <input type="checkbox"/> Other: ____. |

DETAILED ACTION

Status of the Claims

Claims 1-7 are currently pending and are the subject of this Office Action. This is the first Office Action on the merits of the claims.

Priority

The earliest effective U.S. filing date afforded the instantly claimed invention has been determined to be Oct. 20, 2004, the filing date of PCT application PCT/JP04/15481 to which the instant national stage 371 application claims priority. Acknowledgment is made of applicant's claim to foreign priority under 35 U.S.C. 119(a)-(d). The certified copy of the Japanese application was filed with the USPTO on Apr. 12, 2006.

Information Disclosure Statement

References lined-through on the information disclosure statement(s) were not considered because they were not provided in English.

Claim Objections

Claim 1 is objected to because of the following informalities: the designation "pts.wt." is non-standard and should be written out as "parts by weight ". Appropriate correction is required.

Claim Rejections - 35 USC § 112 (2nd Paragraph)

The following is a quotation of the second paragraph of 35 U.S.C. 112:

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The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-7 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. Claim 1 recites "...a proportion of (10-60)/(10-50)/(20-60) by weight" in lines 4-5 of the claim. There are two issues related to the indefiniteness of this recitation. First, no units are specified for the values provided for these proportions. Specifically, it is not clear what type of proportion is intended to be claimed. For instance, the values recited in claim 1 could be intended to be percent by weight or parts by weight. Second, it is unclear to what the proportions are relative by weight. The specification does not provide a sufficient standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Since one of ordinary skill in the art could not be expected to make a reasonable distinction in the absence of further definitions and/or guidance in the specification, the metes and bounds of this claim are indefinite. Claims 2-6 depend from claim 1 and are therefore also indefinite.

However, for the purposes of the rejections to follow, the examiner has interpreted claim 1 to mean "...a proportion of (10-60)/(10-50)/(20-60) parts by weight relative to the total weight of the composition...", with the underlined portions being construed by the examiner.

Additionally, regarding claim 1, it is not clear whether the phrases "i.e.," in lines 2 and 9 of the claim are limitations or whether they are merely listing disclosed examples and/or embodiments. Specifically, the phrase "i.e." is used to further define or exemplify

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the meaning of a prior statement. Description of examples or preferences is properly set forth in the specification rather than the claims. Since it is unclear whether this phrase is a limitation, and thus part of the claimed invention, this phrase renders the claim indefinite. Subsequent claims 2-7 depend on claim 1 and are thus indefinite as well. See MPEP § 2173.05(d).

Claim 4 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claim recites "...wherein the blend amount of the tackifier is in a proportion of 10-80 pts.wt." However, it is unclear to what the 10-80 pts.wt. is relative. Specifically, the term "blend amount" is unclear. For example, the tackifier could be blended with the non-solid isobutylene polymer in a proportion of 10-80 parts per weight or the tackifier could be blended with ALL the ingredients in this proportion. The specification does not provide a sufficient standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. Thus, one of ordinary skill in the art could reasonably construe the tackifier to be in a proportion of 10-80 parts per weight relative to any of the ingredients or combinations thereof in this invention. Since one of ordinary skill in the art could not be expected to make a reasonable distinction in the absence of further definitions and/or guidance in the specification, the metes and bounds of this claim are indefinite.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

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1. This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 1-3, 5, and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipman (U.S. Patent Application Publication No. 2004/0243042; Filed May 20, 2003) (hereinafter Lipman) as evidenced by Yano *et al.* (U.S. Patent No. 5,556,636; Issued Sep. 17, 1996) (hereinafter Yano *et al.*) and by Tabar *et al.* (U.S. Patent No. 4,419,480; Issued Dec. 6, 1983) (hereinafter Tabar *et al.*).

2. A large body of literature exists regarding pressure-sensitive adhesive compositions comprising the components claimed in instant claim 1. For instance, it is known that plasters and other medical adhesives are commonly prepared from, *inter alia*, styrene-isoprene-styrene block copolymers, polyisobutylene, and polyisoprene, and that tackifiers and other softening agents are added to impart a pressure-sensitive adhesion property to these compositions (see Yano *et al.* column 1, lines 21-34). Thus, each of the components recited in claim 1 was well-known in the art at the time of the invention.

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3. Lipman discloses compositions comprising pressure-sensitive adhesives (abstract; paragraphs [0034] and [0035]). Lipman teaches adhesive compositions comprising high molecular weight polyisobutylene (i.e. solid polyisobutylene) (paragraph [0051]; Table at bottom of page 10 and top of page 11) along with polyisoprene and styrene-isoprene-styrene (SIS) copolymers (Table at bottom of page 10 and top of page 11, wherein Kraton D-1161 is a SIS copolymer). Additionally, the adhesive compositions taught by Lipman comprise a liquid rubber component (paragraphs [0009] and [0051]) and a tackifier (paragraph [0070]). The liquid rubber component may be a low molecular weight polyisobutylene (paragraph [0070], see page 7, left column, lines 1-3).

4. Lipman teaches the components of the adhesive compositions in the proportions claimed in instant claim 1. For instance, the adhesives of Lipman are present in an amount from about 10% to 80% of the composition (paragraph [0033]). It is noted that the adhesives can be *one or more* of, *inter alia*, polyisoprene, styrene-isoprene-styrene polymers, and polyisobutylene (paragraph [0034]). Relative to 100% total weight of the composition, the percentages taught by Lipman represent "parts" (e.g. 1% equals 1 part). Based on this evidence and reasoning, Lipman teaches each of polyisoprene, styrene-isoprene-styrene, and polyisobutylene (i.e. solid polyisobutylene) in proportions that may be from about 10% to 80% of the composition (i.e. 10-80 parts). For instance, the teachings of Lipman indicate that these components may be present in amounts, for example, of 10 parts polyisoprene, 20 parts styrene-isoprene-styrene copolymer, and 30 parts solid isobutylene (paragraphs [0034] and [0051]).

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5. Lipman also teaches the inclusion of liquid polyisobutylene (paragraph [0070]) in a range from 1-30 parts relative to the total of the other three components. For instance, the isobutylene could be present in an amount of 10% (i.e. 10 parts), for example. In this case, 10 parts liquid isobutylene corresponds to about 17 parts relative to the other three components when they are present in the proportions discussed above (e.g. 10 parts polyisoprene, 20 parts styrene-isoprene-styrene copolymer, and 30 parts solid isobutylene, for a total of 60 parts). Since Lipman also teaches the use of tackifiers, each element of instant claim 1 is taught in the prior art. However, the difference between Lipman and the instant claims is that Lipman does not explicitly embody the claimed invention with sufficient specificity to be anticipatory.

6. However, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the claimed invention was made to combine all the ingredients as instantly claimed based on the teachings of Lipman to produce the instant invention. As noted above, each of the instantly claimed components of the adhesive composition is well known in the adhesive arts. Furthermore, Lipman teaches that the polyisoprene, styrene-isoprene-styrene copolymer, and isobutylene adhesive components are equivalent and interchangeable (paragraph [0034]; see table at bottom of page 10 and top of page 11, wherein each of the claimed adhesive components are used, often in combination, to prepare an adhesive composition for the same purpose).

7. It is noted that "It is *prima facie* obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose.... [T]he idea of combining them

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flows logically from their having been individually taught in the prior art." *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be *prima facie* obvious.). See MPEP § 2144.06. Furthermore, the MPEP states that the selection of known materials based on their suitability for their intended uses is also *prima facie* obvious. See MPEP § 2144.07. In the instant case, applicants are claiming a combination of known ingredients for the same purpose as that which has been taught in the art. Thus, in light of the teachings of Lipman, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to combine all the ingredients as instantly claimed based on the teachings of Lipman to produce an adhesive composition, reading on instant claim 1.

8. The high molecular weight polyisobutylene taught by Lipman (paragraph [0108]) has a viscosity average molecular weight of not less than 900,000 (see Tabar *et al.* column 8, lines 30-35), reading on instant claim 2.

9. Lipman discloses two embodiments wherein the low molecular weight polyisobutylene has a viscosity average molecular weight of not more than 70,000 (paragraph [0061]), reading on instant claim 3.

10. Lipman teaches the use of tackifiers resins including, *inter alia*, rosin, terpene, and phenol types (paragraph [0070]), reading on instant claim 5.

11. Lipman teaches that the adhesive layer further comprises at least one moisturizing agent (paragraph [0088]; claim 15). These agents include percutaneously

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absorbable compounds such as squalene and lecithin (paragraph [0088]). Squalene, for example, is a known skin-penetrating agent that can be used to treat various skin disorders such as dry skin, psoriasis, and eczema. Thus, these agents can be considered drugs as defined in the instant specification (paragraph [0030]), reading on instant claim 6.

Claims 1, 4, and 7 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lipman in view of Kuniya *et al.* (U.S. Patent Application Publication No. 2002/0045043; Published Apr. 18, 2002) (hereinafter Kuniya *et al.*)

12. Lipman teaches the pressure-sensitive adhesive composition of instant claim 1 as applied above. Lipman does not teach the tackifier in a proportion of 10-80 parts by weight. Further, while Lipman teaches the pressure-sensitive adhesive composition adhered to a fluid absorbing layer and a moldable adhesive layer (paragraph [0092] and Figure 4), Lipman does not teach the adhesive composition laminated on a backing and covered with a liner.

13. Kuniya *et al.* disclose pressure-sensitive adhesive compositions comprising a solid rubber component and a liquid rubber component (abstract). The adhesive composition of Kuniya *et al.* comprises components of instant claim 1, including styrene-isoprene-styrene copolymers (paragraphs [0016] and [0017]) in combination with other isoprene polymers, such as styrene-isoprene copolymers, which are a type of polyisoprene (paragraph [0018]). Kuniya *et al.* further teach the use of a liquid rubber component such as polyisobutylene (paragraph [0019]) and tackifiers (paragraphs [0021] and [0022]).

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14. Regarding claim 4, there is an issue of indefiniteness with this claim as noted above under 112 2nd paragraph rejections. For the purpose of this rejection the claim has been interpreted to mean 10-80 pts by weight relative to the other rubber components in the composition. Kuniya *et al.* teach the inclusion of the tackifier in an amount from 25-80 parts by weight based on the total amount of the other rubber components in the adhesive composition (abstract). Kuniya *et al.* teach that using a high proportion of tackifier improves the adhesion force of the composition (paragraph [0009]). Thus, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to include a high proportion of tackifier in the compositions taught by Lipman, in order to improve the adhesive force of the composition as taught by Kuniya *et al.*, reading on instant claim 4.

15. Kuniya *et al.* teach laminating the adhesive composition of their invention to a backing film (paragraph [0014]; claim 7), which may be one of a plurality of such films (paragraph [0028]). Furthermore, Kuniya *et al.* teach that the backing may be lined with polypropylene tape (i.e. a liner) (paragraph [0054]). As stated above, Lipman teaches applying the adhesive composition to a backing (paragraph [0092]; figures 4 and 5). In light of the teachings of Kuniya *et al.*, it would have been *prima facie* obvious to one of ordinary skill in the art at the time of the invention to laminate the adhesive composition of Lipman onto a backing, which is covered by a liner. One would have been motivated to do so to produce a marketable final product comprising the adhesive composition, such as the pressure-sensitive adhesive sheets of Kuniya *et al.*, reading on instant claim 7.

Conclusion

No claims are currently allowable.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Kevin S. Orwig whose telephone number is (571)270-5869. The examiner can normally be reached Monday-Friday 7:00 am-4:00 pm (with alternate Fridays off). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sharmila Landau can be reached Monday-Friday 8:00 am-5:00 pm at (571)272-0614. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

KSO

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Supervisory Patent Examiner, Art Unit 1611